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Attorney

Docket No.: BU-022XX

DECLARATION AND POWER OF ATTORNEY

As a below-named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

METHOD FOR CONDUCTING CLINICAL TRIALS OVER THE INTERNET

the specification of which (check one):

☒ [X] is attached hereto. ☐ [ ] was filed \_\_\_\_\_ as Application No. amended on (if applicable).

☐ [ ] was filed as PCT International Application No. \_\_\_\_\_ on \_\_\_\_\_, and was amended under PCT Article 19 on \_\_\_\_\_ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations §1.56(a).

I hereby claim foreign priority benefits under Title 35, USC §119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

| <u>Prior Foreign Application(s)</u> |                    | <u>Date Filed</u>         | <u>Priority Claimed</u>             |                                    |
|-------------------------------------|--------------------|---------------------------|-------------------------------------|------------------------------------|
| _____<br>(Number)                   | _____<br>(Country) | _____<br>(Day/Month/Year) | <input type="checkbox"/> [ ]<br>Yes | <input type="checkbox"/> [ ]<br>No |
| _____<br>(Number)                   | _____<br>(Country) | _____<br>(Day/Month/Year) | <input type="checkbox"/> [ ]<br>Yes | <input type="checkbox"/> [ ]<br>No |

I hereby claim the benefit under Title 35, USC §119(e) of any United States provisional application(s) listed below:

|                                    |                                 |
|------------------------------------|---------------------------------|
| 60/131,528<br>(Application Number) | April 29, 1999<br>(Filing Date) |
| _____<br>(Application Number)      | _____<br>(Filing Date)          |

Express Mail Number

EL418427930US

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We hereby claim the benefit under Title 35 USC §120 of any United States application(s) listed below and insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35 USC §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application No.)

(Filing Date)

(Patented/pending/abandoned)

(Application No.)

(Filing Date)

(Patented/pending/abandoned)

**POWER OF ATTORNEY:** As a named inventor, I hereby appoint the following attorney(s) to prosecute this application and transact all business connected therewith in the Patent and Trademark Office, and to file with the USRO any International Application based thereon.

Stanley M. Schurgin, Reg. No. 20,979  
Charles L. Gagnebin III, Reg. No. 25,467  
Paul J. Hayes, Reg. No. 28,307  
Victor B. Labovici, Reg. No. 30,864

Eugene A. Feher, Reg. No. 33,171  
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of Sole/First Inventor: Timothy E. McAlindon

|   |                        |  |
|---|------------------------|--|
| City of Residence<br>Belmont  | State or Country<br>MA | Country of Citizenship<br>U.K.                   |
| Post Office Address<br>6 Winn St.   | City<br>Belmont        | State or Country Zip Code<br>Massachusetts 02478 |
| Signature: (Please sign and date in permanent ink.)<br>X <i>Tim McAlindon</i> |                        | Date signed:<br>X 4/26/00                        |



**COPY**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Timothy E. McAlindon ATTORNEY  
DOCKET NO.: BU-022XQ800  
APPLICATION NO.: 60/131,528 EXAMINER:  
FILED: April 29, 1999 GROUP NO.:  
PATENT NO.: ISSUED:  
ENTITLED: METHOD FOR CONDUCTING CLINICAL TRIALS ENTIRELY OVER THE INTERNET

VERIFIED STATEMENT AS SMALL ENTITY

Assistant Commissioner for Patents  
Washington, D.C. 20231

Six

**THE UNDERSIGNED DECLARE(S):**

Exclusive rights in the above-identified invention reside in the "small entity(ies)" defined and named below or in a Verified Statement as Small Entity filed by other such small entity(ies), and "small entity" fees are appropriate. Qualification as a small entity is based upon the appropriately checked statements below:

**[ ] INDEPENDENT INVENTOR(S)**

The below-signing independent inventor(s) has (have) not assigned, granted, conveyed or licensed, and is (are) under no obligation under contract or law to assign, grant, convey or license any rights in the invention to any person who could not likewise be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

**[ ] SMALL BUSINESS CONCERN**

The below-identified small business concern qualifies as a small business as defined in 13 CFR 121.1301 through 121.1305, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, in that the number of employees, including those of its affiliates, which does not exceed 500 persons, and it has not assigned, granted, conveyed or licensed, and is under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

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Concerns are affiliates of each other when, either directly or indirectly, one concern controls or has the power to control the other, or a third party controls or has the power to control both. The number of employees of the business concern is the average over the fiscal year of the persons employed during each of the pay periods of the fiscal year. Employees are those persons employed on a full-time, part-time or temporary basis during the previous fiscal year of the concern.


**[X] NONPROFIT ORGANIZATION** (Check additional applicable box.)

The below-identified nonprofit organization qualifies as a small entity under 37 CFR 1.9(e) in that it constitutes:

1. ☒ a university or other institution of higher education located in any country; or
2. ☐ an organization of the type described in Section 501(c)(3) of the Internal Revenue Code of 1954 (26 USC 501(c)(3)) and exempt from taxation under Section 501(a) of the Internal Revenue Code (26 USC 501(a)); or
3. ☐ any nonprofit scientific or educational organization qualified under a nonprofit organization statute of a state of the United States (35 USC 201(i)); or
4. ☐ any nonprofit organization located in a foreign country which would qualify as a nonprofit organization under paragraphs (e)(2) or (3) of Rule 1.9 if it were located in the United States.

The undersigned acknowledge(s) the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate (37 CFR 1.28(b)).

The below-signing individual(s) hereby declare(s) that (he, she, they) are authorized to execute this statement on behalf of the small entity.

|  |                               |
|--|-------------------------------|
| Name of Small Entity: (Independent Inventor/Small Business/Nonprofit)<br>The Trustees of Boston University.                                      |                               |
| Address of Small Entity: (Street, City, State or Country, Zip Code)<br>147 Bay State Road  |                               |
| Name of Person Signing: (Small Business/Nonprofit)<br>Matthew J. Burns   |                               |
| Title of Person Signing: (Small Business/Nonprofit)<br>Assistant Treasurer   |                               |
| Signature: (Please sign and date in permanent ink.)<br><br>X  | Date signed:<br><br>X 5/20/99 |